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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PREBILIC, PAUL B	

ART UNIT	PAPER NUMBER
3738	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/029,872

Applicant(s)

PUGH ET AL.

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6,10,12,13,22,23,25-29,32-35,37 and 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6,10,12,13,22,23,25-27,29,32-35,37 and 38 is/are rejected.
- 7) ☒ Claim(s) 28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after a decision by the Board of Patent Appeals and Interferences, but before the filing of a Notice of Appeal to the Court of Appeals for the Federal Circuit or the commencement of a civil action. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on April 23, 2007 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6, 12, 13, 22, 23, 25, 32, 34, and 38 are rejected under 35 U.S.C. 102(b)* as being anticipated by Ruys (article entitled "Silicone-doped Hydroxyapatite"). Ruys anticipates the claim language where the sol-gel of Ruys is a uniform mixture of hydroxyapatite and silicone which is converted to alpha-TCP by sintering as claimed; see page 71 (the abstract), page 74, last paragraph, and page 76 (the section entitled "Silicon Addition"). The result of Ruys' process is a bulk material. Furthermore, since the material of Ruys is the same as that claimed, it would inherently be insoluble in physiological fluids and have the same resorbability and *in vivo* response

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as claimed because it is the same material as that claimed alpha-tricalcium phosphate; see page 72.

*The Examiner posits that the effective filing date of the present claims is August 30, 1996 because the provisional application 60/003,157 and the earlier parent application 08/576,238 only disclosed silicon entities and not other types of entities as the present claims do. Therefore, the present claims have a later filing date because the term stabilization or the meaning of stabilization entities was broadened from the meaning it had in the parent application filed before August 30, 1996.

With regard to claim 2, the higher concentration of silicone results in primarily alpha-TCP (see page 71 of Ruys), and thus, the Examiner posits that the 50 mol% material of Ruys would inherently result in a primarily alpha-TCP material after sintering.

With regard to claim 12, the material of Ruys is the same as that claimed and disclosed, and thus, it inherently has the same solubility properties such that this claim language is fully met.

With regard to claim 25, the material of Ruys is the same as that claimed and disclosed, and thus, it inherently has the same structural properties of Figure 14 as claimed. It is noted that Figure 14 is of very poor quality such that details thereof are not readily discernable.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 10 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruys (article) alone.

With regard to claim 10, Ruys uses tetraethyl orthosilicate instead of tetrapropyl orthosilicate as claimed. However, since tetraethyl orthosilicate and tetrapropyl orthosilicate are homologues of each other, one would expect them to be quite similar in their function and perform quite similarly in the claimed invention. For this reason, it is the Examiner's position that it would have been prima facie obvious to substitute tetrapropyl orthosilicate for tetraethyl silicate in the Ruys invention because of the quite similar structure and function.

With regard to claim 26, Ruys fails to disclose the particle size as claimed even though it was disclosed as being crushed and pelletized; see page 76. However, since it was known, in the art, to crush and pelletize the same material as claimed, it is the Examiner's position that the mere selection of a particle size would have been considered prima facie obvious to an ordinary artisan because it has not shown to provide some advantage, solve some stated problem or used for some particular purpose, the Examiner takes the position that it would have been considered prima facie obvious to use the claimed particle size with the Ruys composition; see MPEP 2144.04.

In *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

Claims 27, 29, 35, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruys (article) in view of Davies (WO 94/26872). Ruys meets the claim language except for the presence of bone cells or their excreted materials, but Ruys envisions the need to assess the material for bone cell activity via clinical trials; see page 79. Davies teaches that it was known to assess bone cell activity by culturing bone cells on a support coated with a thin film of a sol-gel; see the abstract, page 1, lines 4-9, and column 4, lines 21-28, especially lines 21-25. Therefore, it would have been prima facie obvious to assess the bone cell activity of the Ruys composition, as taught by Davies, in order to see how effective it is as a bone growth or ingrowth promoter which was the desire of Ruys; see page 79 of Ruys under the heading "Conclusions."

With regard to claims 27 and 29, the Examiner posits that the claimed matrix would inherently be formed in the Davies modified Ruys device due to the same device being exposed to the same cells for a sufficient time for such matrix to form; see page 11, lines 17-31 of Davies.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ruys (article) in view of Kijima et al (US 4,983,182). Ruys meets the claim language as set forth in the claim 1 rejection above but fails to disclose a coated form of the composition as claimed. However, Kijima teaches that it was known put similar tricalcium phosphate coatings on implants in order to make the surface biologically active such that bonding of the implant to the patient is improved; see the abstract and column 1, lines 5-27. Therefore, it is the Examiner's position that it would have been prima facie obvious to

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use the Ruys material as a coating for an implant in order to make the implant more bioactive as taught by Kijima.

Allowable Subject Matter

Claim 28 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Argument

Beginning on page 6 of the Response filed April 23, 2006, the Applicants argue that the process used to make the Ruys material is a stir/boil method that is designed to keep the TCP content to a minimum. In response, the Examiner asserts that alpha-TCP is still present even if kept to a minimum. Furthermore, keeping TCP to a minimum is merely a preference when lower biodegradability is desired; it does not mean that the alternative is unacceptable. Clearly, in both alternatives, alpha-TCP is present, and thus, the claim language is clearly anticipated or rendered obvious over Ruys.

On page 8 of the Response, the Applicants argue that Ruys states that any residual TCP would be soluble. The Examiner does not see where Ruys states that the TCP would be soluble and believes that the Applicants are again confusing solubility with degradability. "Soluble" is denoted as "*capable of mixing with a liquid (dissolving) to form a homogeneous mixture (solution)*"; Hackh's Chemical Dictionary, Fourth Edition, (1969), p. 624. "Biodegradable", on the other hand, is denoted as "*Describing a substance that can be decomposed by biological action*"; see Hackh's *supra*, p. 97. Therefore, to be "soluble" the molecules of a material merely need to physically

separate into the solvent. However, biodegradability requires the material to be decomposed or chemically broken down to separate portions thereof from the whole by the actions of a biological organism or enzyme. For this reason, biodegradability is synonymous with resorbability by biological action.

Applicants argue that they “were the first to discover that the presence of stabilized entities can stabilize the composition and prevent its degradation in physiological fluids.” However, the Examiner counters that the discovery of a new property does not render an otherwise old composition patentable; see MPEP 2112 (I), which is incorporated herein by reference. Applicants have provided no evidence that would suggest that their composition is any different from that disclosed by Ruys. Furthermore, the Board of Appeals agreed with the Examiner in the decision rendered February 26, 2007; see page 4, last paragraph of the decision. The rationale used in the Board Decision is hereby incorporated herein by reference since it is highly relevant to the present fact pattern.

Furthermore, claim 1 requires that the stabilized tricalcium phosphate is resorbable by osteoclasts, i.e. by biological action of the bone cells. Similarly, Ruys prefers low dopant levels to keep tricalcium phosphate “to a minimum and so eliminate the possibility of biodegradability *in vivo*”; see page 79, “Conclusions” section. For this reason, it is clear that Ruys also discloses that the tricalcium phosphate is resorbable or biodegradable and not soluble as defined by Hackh’s. Therefore, the Examiner asserts that Ruys discloses an insoluble TCP to the extent that such language can be given patentable weight. Not that this limitation is needed to meet the claim language, but

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Ruys discloses a range of silicone, which avoids forming biodegradable TCP (tricalcium phosphate); see the last paragraph on page 71. For this reason, the insoluble tricalcium phosphate called for in claim 1 is fully met by Ruys even when the term "insoluble" is interpreted to mean non-resorbable or non-biodegradable.

Although the Applicants have had several opportunities to do so, they have never provided evidence of this alleged difference between the Ruys material and the material of the presently claimed invention. MPEP 2112 is incorporated herein by reference as follows:

ONCE A REFERENCE TEACHING PRODUCT APPEARING TO BE SUBSTANTIALLY IDENTICAL IS MADE THE BASIS OF A REJECTION, AND THE EXAMINER PRESENTS EVIDENCE OR REASONING TENDING TO SHOW INHERENCY, THE BURDEN SHIFTS TO THE APPLICANT TO SHOW AN UNOBTAINABLE DIFFERENCE "[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, on prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. In re Fitzgerald, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

Applicants argue that there is no motivation to modify Ruys to arrive at the presently claimed invention. However, the Examiner asserts that the difference between Ruys and the claimed invention is so slight that it would have been *prima facie* obvious to make the modification suggested. Since Applicants have provided no reason why such a modification was made, the Examiner asserts that it is *prima facie* obvious to do so.

The Applicants argue that Ruys teaches away from the claimed invention because it prefers low dopant levels. However, the Examiner asserts that Ruys makes a wide range of silicon-doped materials for testing purposes. However, Ruys suggests that lower dopant levels would be better to avoid biodegradability. This is the same reason that the Applicants want an insoluble stabilized material, that is, to form a stable implant material as a scaffold or lattice for new bone growth. For this reason, the Examiner asserts that both the Applicants and Ruys are teaching the same thing, but have merely explained it in a different way.

Next, the Applicants argue that Ruys does not test the material in any manner so he cannot suggest the use of its material as an implant. However, it is clear that Ruys suggests that this should be done; see the "Conclusions" section. This is all that is needed to form a nexus with Davies. Furthermore, upon reading the Applicants disclosure, it was noted that there is no evidence that the Applicants ever tested their material in any manner as an implant.

The Applicants merely argue that Kijima fails to cure what they see as the deficiencies of Ruys. However, Kijima was not applied to demonstrate the obviousness of the argued features, and thus, these arguments are not relevant to the rejection as it is set forth. Since Ruys does disclose every limitation of claim 1, as explained above, the Applicants arguments are considered unpersuasive. Furthermore, to argue that the secondary reference does not have features that it is not said to teach is not relevant or persuasive with respect to the rejection.

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Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilic
Primary Examiner
Art Unit 3738